Patent Application

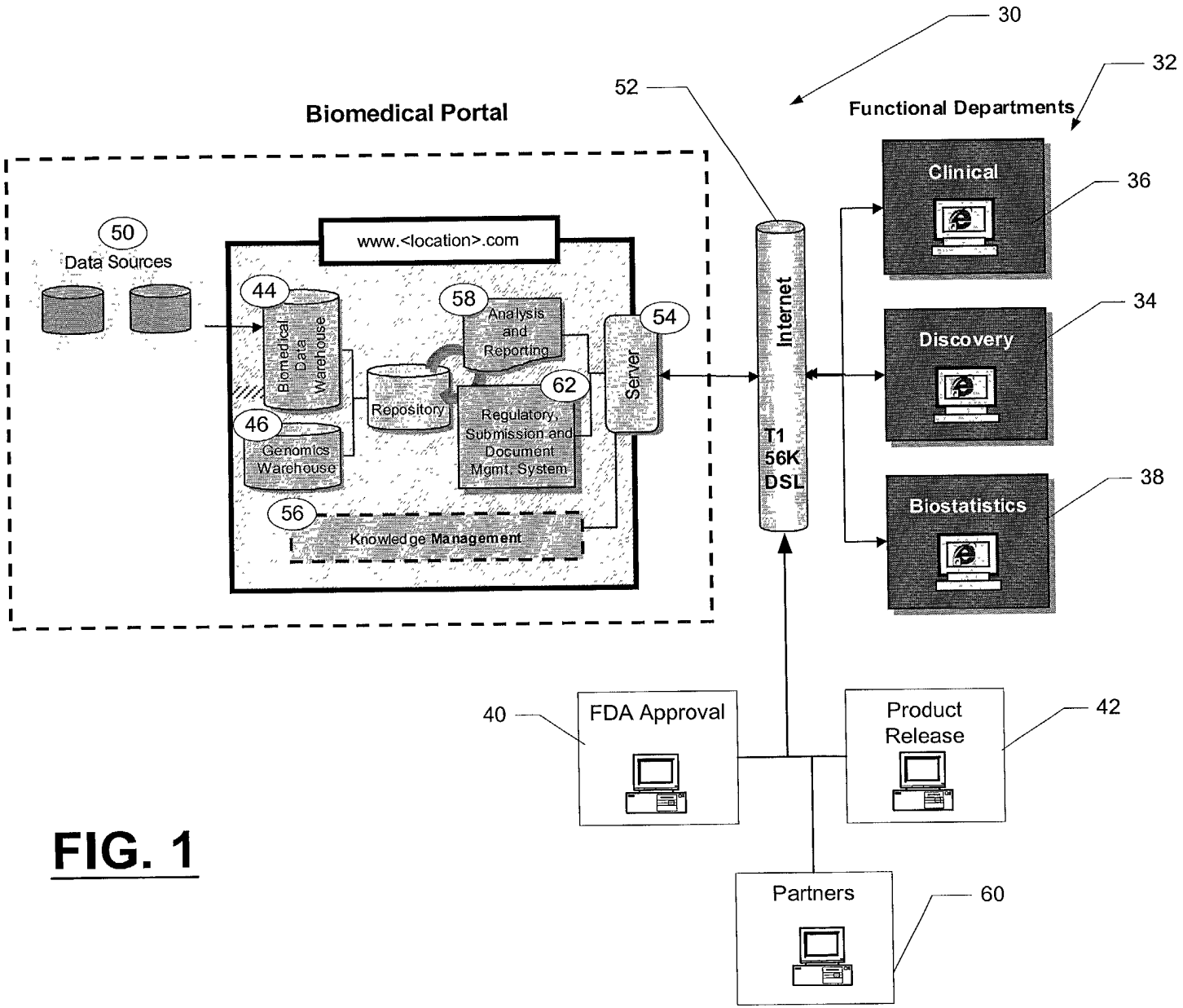


FIG. 1

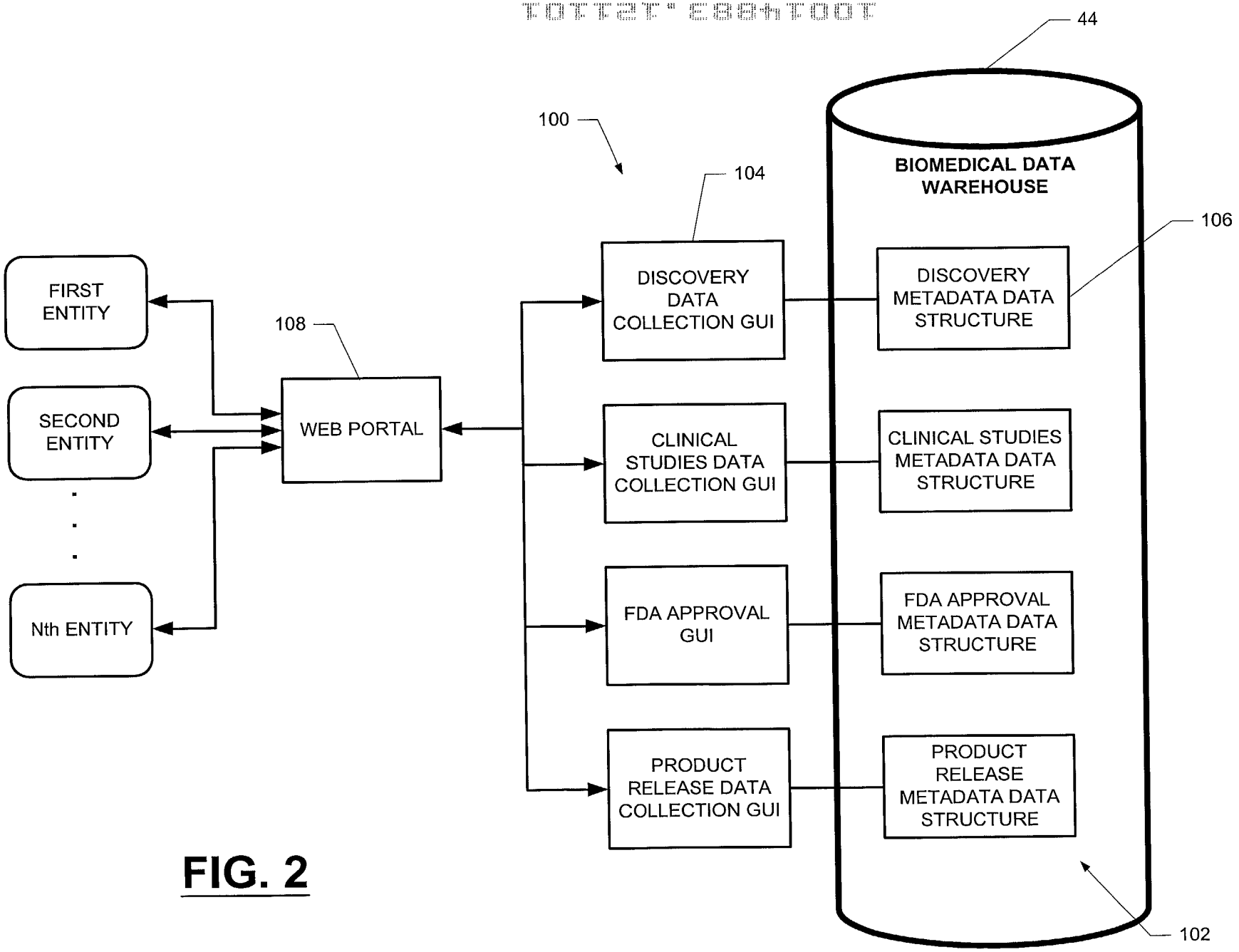

44
100
BIOMEDICAL DATA WAREHOUSE
104
106
FIRST ENTITY
SECOND ENTITY
Nth ENTITY
108
WEB PORTAL
DISCOVERY DATA COLLECTION GUI
CLINICAL STUDIES DATA COLLECTION GUI
FDA APPROVAL GUI
PRODUCT RELEASE DATA COLLECTION GUI
DISCOVERY METADATA DATA STRUCTURE
CLINICAL STUDIES METADATA DATA STRUCTURE
FDA APPROVAL METADATA DATA STRUCTURE
PRODUCT RELEASE METADATA DATA STRUCTURE
102

FIG. 2

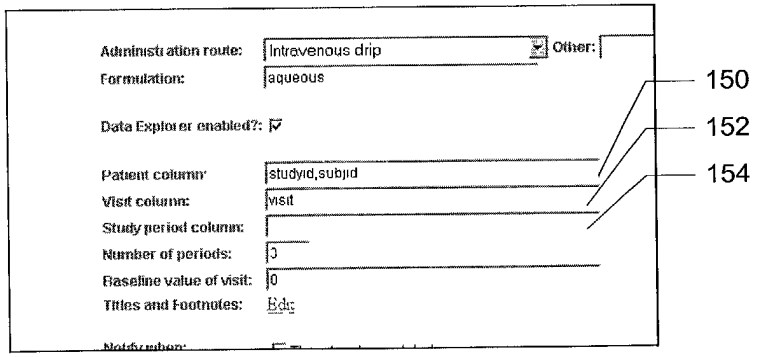

Administration route:
Intravenous drip
Other:
Formulation:
aqueous
Data Explorer enabled?:
Patient column:
studyid,subjid
Visit column:
visit
Study period column:
Number of periods:
0
Baseline value of visit:
0
Titles and Footnotes:
Edit
150
152
154

FIG. 3

patent application

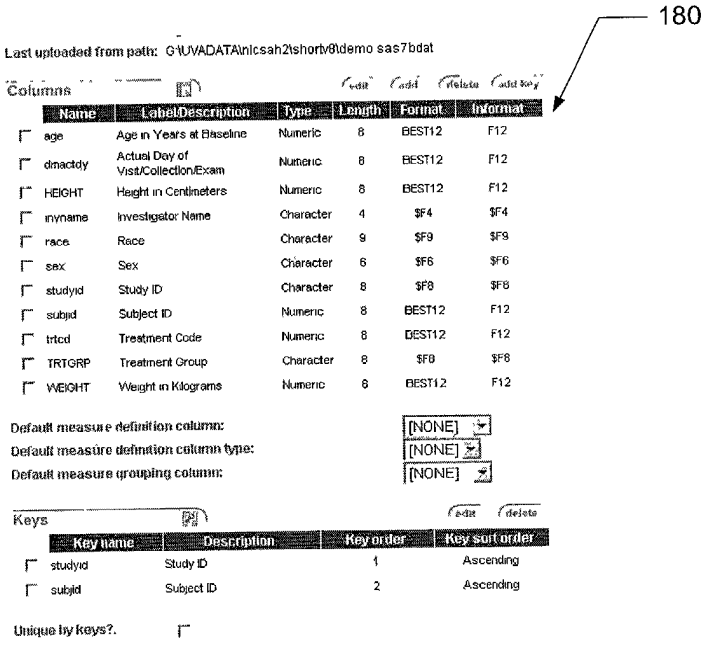


FIG. 4

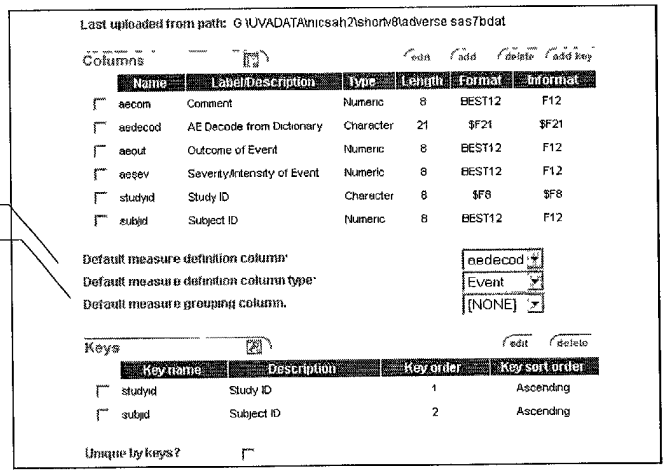

Last uploaded from path: G:\UVADATA\ncsah2\short8\adverse sas7bdat
Columns
edit
add
delete
add key
Name
Label/Description
Type
Length
Format
Informat
aecom
Comment
Numeric
8
BEST12
F12
aedecod
AE Decode from Dictionary
Character
21
$F21
$F21
aeout
Outcome of Event
Numeric
8
BEST12
F12
aesev
Severity/Intensity of Event
Numeric
8
BEST12
F12
studyid
Study ID
Character
8
$F8
$F8
subjid
Subject ID
Numeric
8
BEST12
F12
Default measure definition column:
aedecod
Default measure definition column type:
Event
Default measure grouping column:
[NONE]
Keys
edit
delete
Key name
Description
Key order
Key sort order
studyid
Study ID
1
Ascending
subjid
Subject ID
2
Ascending
Unique by keys?
190
192

FIG. 5

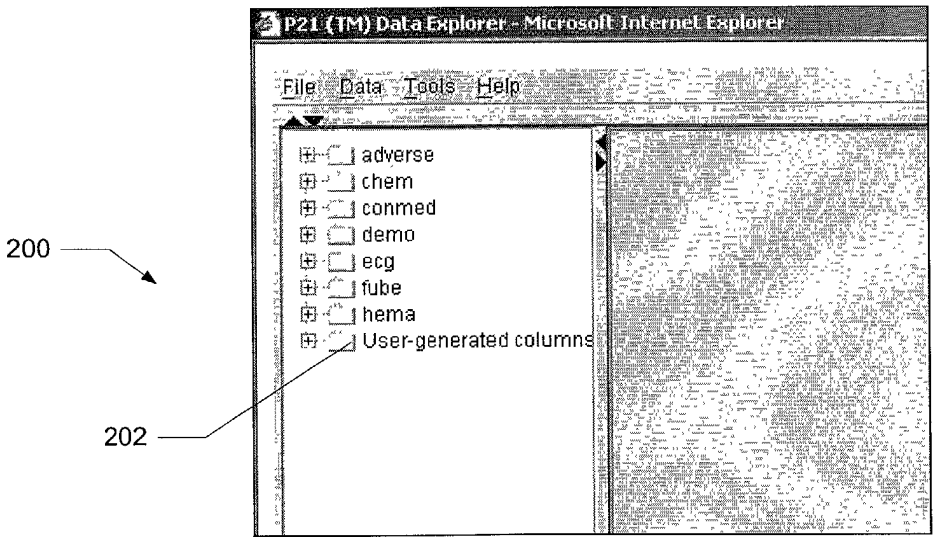

P21 (TM) Data Explorer - Microsoft Internet Explorer
File Data Tools Help
adverse
chem
conmed
demo
ecg
fube
hema
User-generated columns
200
202

FIG. 6

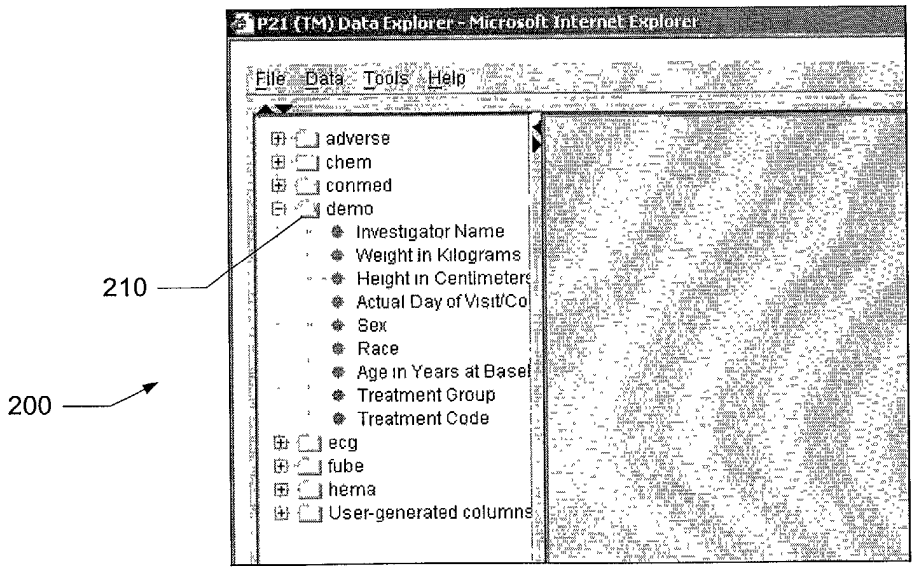

P21 (TM) Data Explorer - Microsoft Internet Explorer
File Data Tools Help
adverse
chem
conmed
demo
Investigator Name
Weight in Kilograms
Height in Centimeters
Actual Day of Visit/Co
Sex
Race
Age in Years at Base
Treatment Group
Treatment Code
ecg
fube
hema
User-generated columns
210
200

FIG. 7

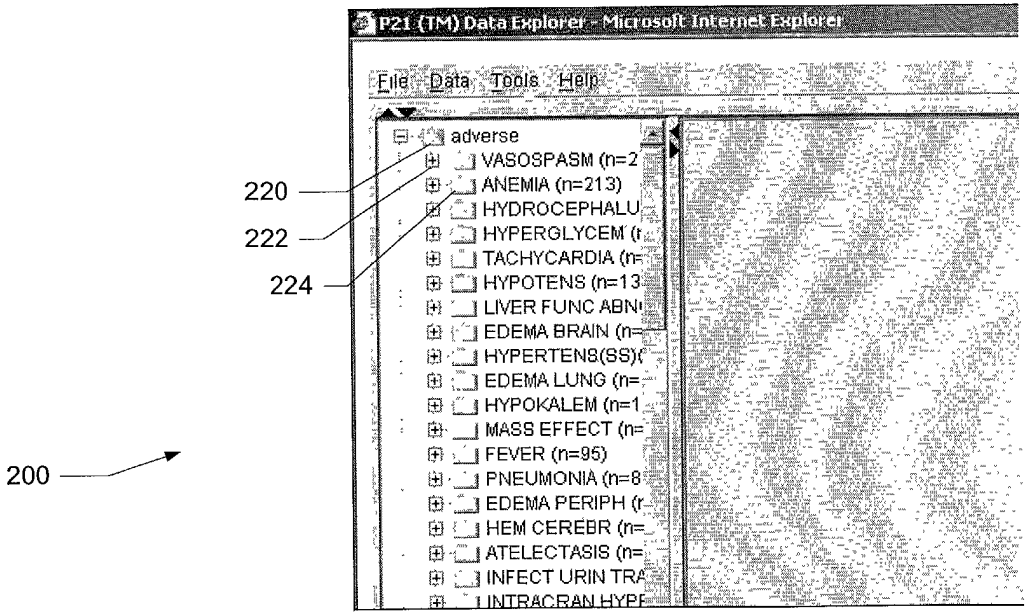

P21 (TM) Data Explorer - Microsoft Internet Explorer
File Data Tools Help
adverse
VASOSPASM (n=2
ANEMIA (n=213)
HYDROCEPHALU
HYPERGLYCEM (r
TACHYCARDIA (n=
HYPOTENS (n=13
LIVER FUNC ABN
EDEMA BRAIN (n=
HYPERTENS(SS)(
EDEMA LUNG (n=
HYPOKALEM (n=1
MASS EFFECT (n=
FEVER (n=95)
PNEUMONIA (n=8
EDEMA PERIPH (r
HEM CEREBR (n=
ATELECTASIS (n=
INFECT URIN TRA
INTRACRAN HYPE
220
222
224
200

FIG. 8

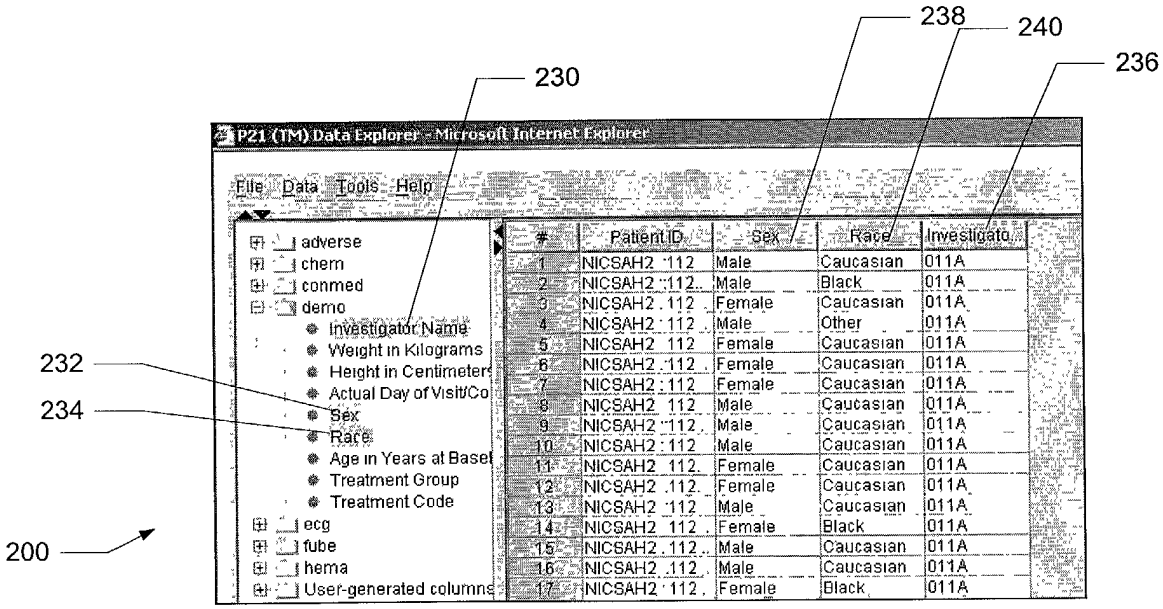

238
240
236
230
232
234
200
P21 (TM) Data Explorer - Microsoft Internet Explorer
File Data Tools Help
adverse
chem
conmed
demo
Investigator Name
Weight in Kilograms
Height in Centimeters
Actual Day of Visit/Co
Sex
Race
Age in Years at Baseli
Treatment Group
Treatment Code
ecg
fube
hema
User-generated columns
Patient ID Sex Race Investigato
1 NICSAH2 112 Male Caucasian 011A
2 NICSAH2 112 Male Black 011A
3 NICSAH2 112 Female Caucasian 011A
4 NICSAH2 112 Male Other 011A
5 NICSAH2 112 Female Caucasian 011A
6 NICSAH2 112 Female Caucasian 011A
7 NICSAH2 112 Female Caucasian 011A
8 NICSAH2 112 Male Caucasian 011A
9 NICSAH2 112 Male Caucasian 011A
10 NICSAH2 112 Male Caucasian 011A
11 NICSAH2 112 Female Caucasian 011A
12 NICSAH2 112 Female Caucasian 011A
13 NICSAH2 112 Male Caucasian 011A
14 NICSAH2 112 Female Black 011A
15 NICSAH2 112 Male Caucasian 011A
16 NICSAH2 112 Male Caucasian 011A
17 NICSAH2 112 Female Black 011A

FIG. 9

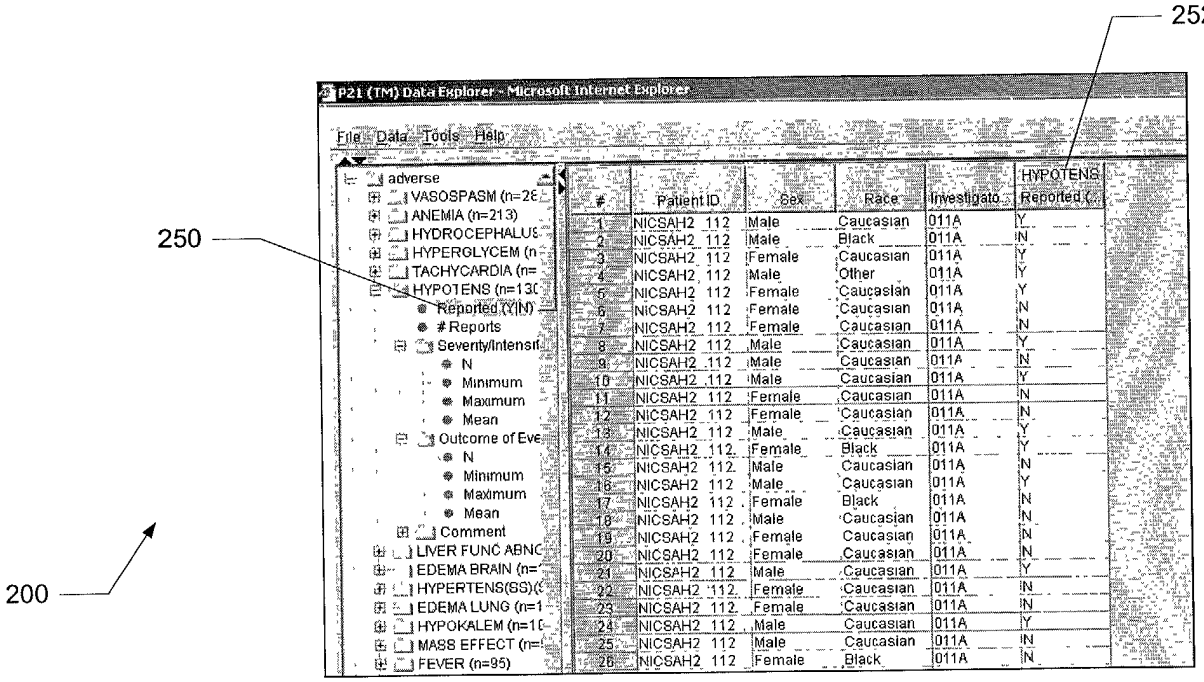

252
250
200
P21 (TM) Data Explorer - Microsoft Internet Explorer
File Data Tools Help
adverse
VASOSPASM (n=28
ANEMIA (n=213)
HYDROCEPHALUS
HYPERGLYCEM (n
TACHYCARDIA (n=
HYPOTENS (n=13(
Reported (Y/N)
Reports
Severity/Intensi
N
Minimum
Maximum
Mean
Outcome of Eve
N
Minimum
Maximum
Mean
Comment
LIVER FUNC ABNC
EDEMA BRAIN (n=
HYPERTENS(SS)(
EDEMA LUNG (n=1
HYPOKALEM (n=1(
MASS EFFECT (n=
FEVER (n=95)
| Patient ID | Sex | Race | Investigato | HYPOTENS Reported (
1 | NICSAH2_112 | Male | Caucasian | 011A | Y
2 | NICSAH2_112 | Male | Black | 011A | N
3 | NICSAH2_112 | Female | Caucasian | 011A | Y
4 | NICSAH2_112 | Male | Other | 011A | Y
5 | NICSAH2_112 | Female | Caucasian | 011A | Y
6 | NICSAH2_112 | Female | Caucasian | 011A | N
7 | NICSAH2_112 | Female | Caucasian | 011A | N
8 | NICSAH2_112 | Male | Caucasian | 011A | Y
9 | NICSAH2_112 | Male | Caucasian | 011A | N
10 | NICSAH2_112 | Male | Caucasian | 011A | Y
11 | NICSAH2_112 | Female | Caucasian | 011A | N
12 | NICSAH2_112 | Female | Caucasian | 011A | N
13 | NICSAH2_112 | Male | Caucasian | 011A | Y
14 | NICSAH2_112 | Female | Black | 011A | Y
15 | NICSAH2_112 | Male | Caucasian | 011A | N
16 | NICSAH2_112 | Male | Caucasian | 011A | Y
17 | NICSAH2_112 | Female | Black | 011A | N
18 | NICSAH2_112 | Male | Caucasian | 011A | N
19 | NICSAH2_112 | Female | Caucasian | 011A | N
20 | NICSAH2_112 | Female | Caucasian | 011A | N
21 | NICSAH2_112 | Male | Caucasian | 011A | Y
22 | NICSAH2_112 | Female | Caucasian | 011A | N
23 | NICSAH2_112 | Female | Caucasian | 011A | N
24 | NICSAH2_112 | Male | Caucasian | 011A | Y
25 | NICSAH2_112 | Male | Caucasian | 011A | N
26 | NICSAH2_112 | Female | Black | 011A | N

FIG. 10

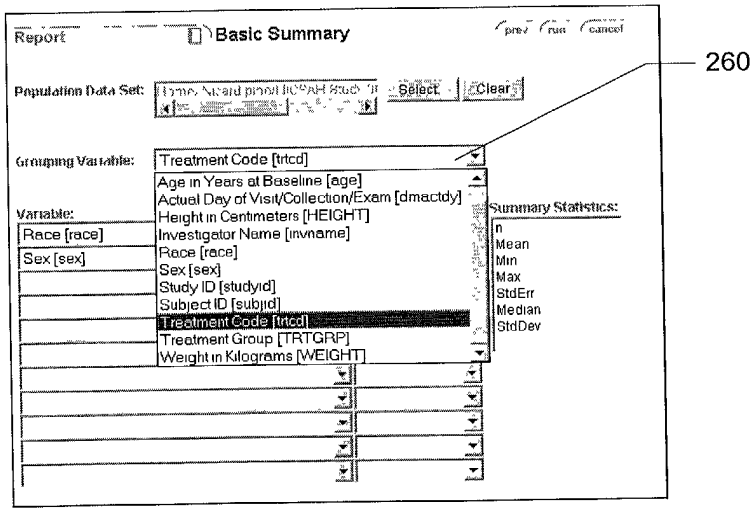

Report
Basic Summary
prev
run
cancel
Population Data Set:
Select
Clear
Grouping Variable:
Treatment Code [trtcd]
Variable:
Race [race]
Sex [sex]
Age in Years at Baseline [age]
Actual Day of Visit/Collection/Exam [dmactdy]
Height in Centimeters [HEIGHT]
Investigator Name [invname]
Race [race]
Sex [sex]
Study ID [studyid]
Subject ID [subjid]
Treatment Code [trtcd]
Treatment Group [TRTGRP]
Weight in Kilograms [WEIGHT]
Summary Statistics:
n
Mean
Min
Max
StdErr
Median
StdDev
260

FIG. 11

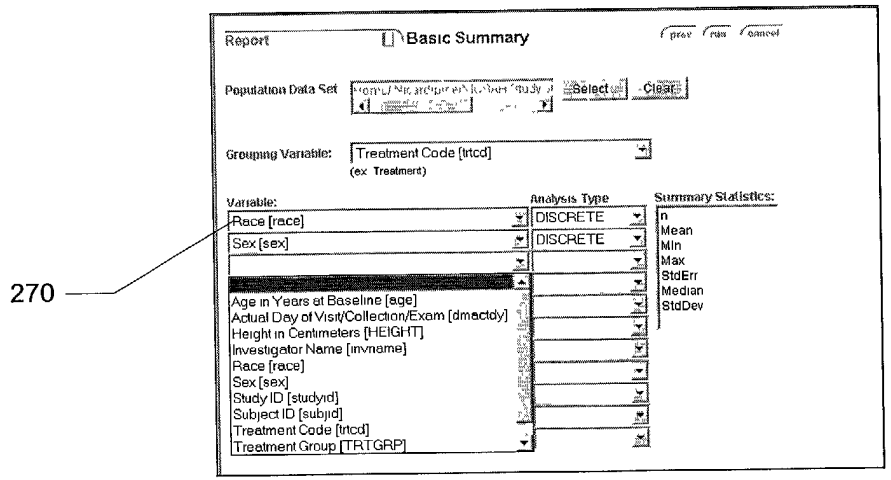
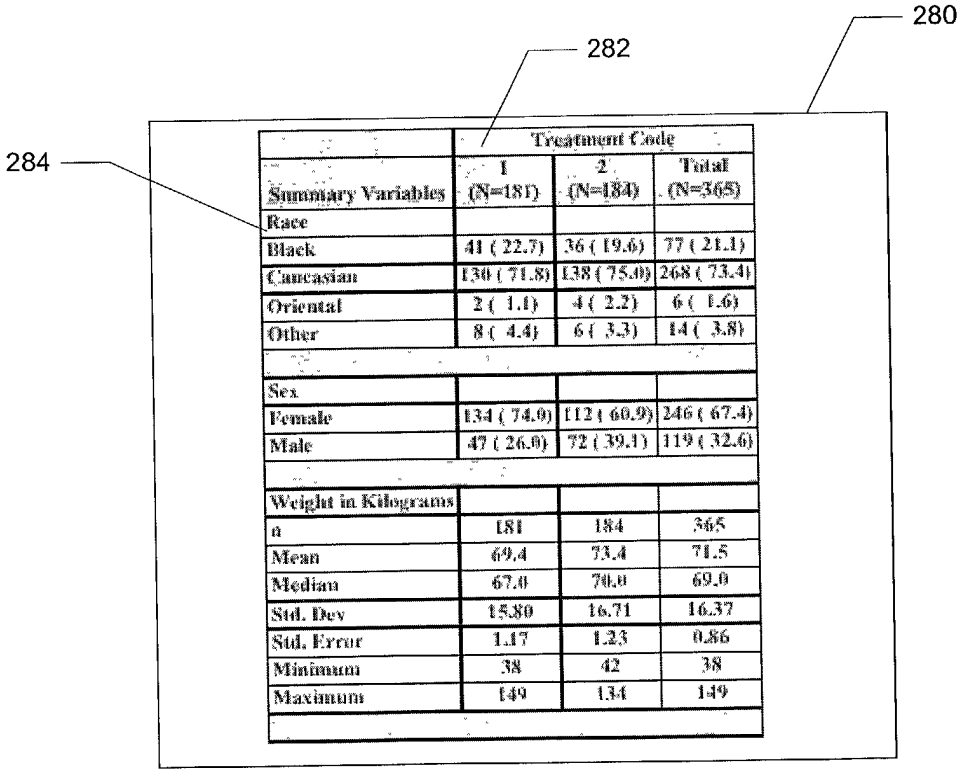

Report
Basic Summary
Prev
Run
Cancel
Population Data Set
Select
Clear
Grouping Variable:
Treatment Code [trtcd]
(ex Treatment)
Variable:
Analysis Type
Summary Statistics:
Race [race]
DISCRETE
Sex [sex]
DISCRETE
n
Mean
Min
Max
StdErr
Median
StdDev
Age in Years at Baseline [age]
Actual Day of Visit/Collection/Exam [dmactdy]
Height in Centimeters [HEIGHT]
Investigator Name [invname]
Race [race]
Sex [sex]
Study ID [studyid]
Subject ID [subjid]
Treatment Code [trtcd]
Treatment Group [TRTGRP]
270

FIG. 12



	Treatment Code		
Summary Variables	1 (N=181)	2 (N=184)	Total (N=365)
Race			
Black	41 (22.7)	36 (19.6)	77 (21.1)
Caucasian	130 (71.8)	138 (75.0)	268 (73.4)
Oriental	2 (1.1)	4 (2.2)	6 (1.6)
Other	8 (4.4)	6 (3.3)	14 (3.8)
Sex			
Female	134 (74.0)	112 (60.9)	246 (67.4)
Male	47 (26.0)	72 (39.1)	119 (32.6)
Weight in Kilograms			
n	181	184	365
Mean	69.4	73.4	71.5
Median	67.0	70.0	69.0
Std. Dev	15.80	16.71	16.37
Std. Error	1.17	1.23	0.86
Minimum	38	42	38
Maximum	149	134	149

FIG. 13

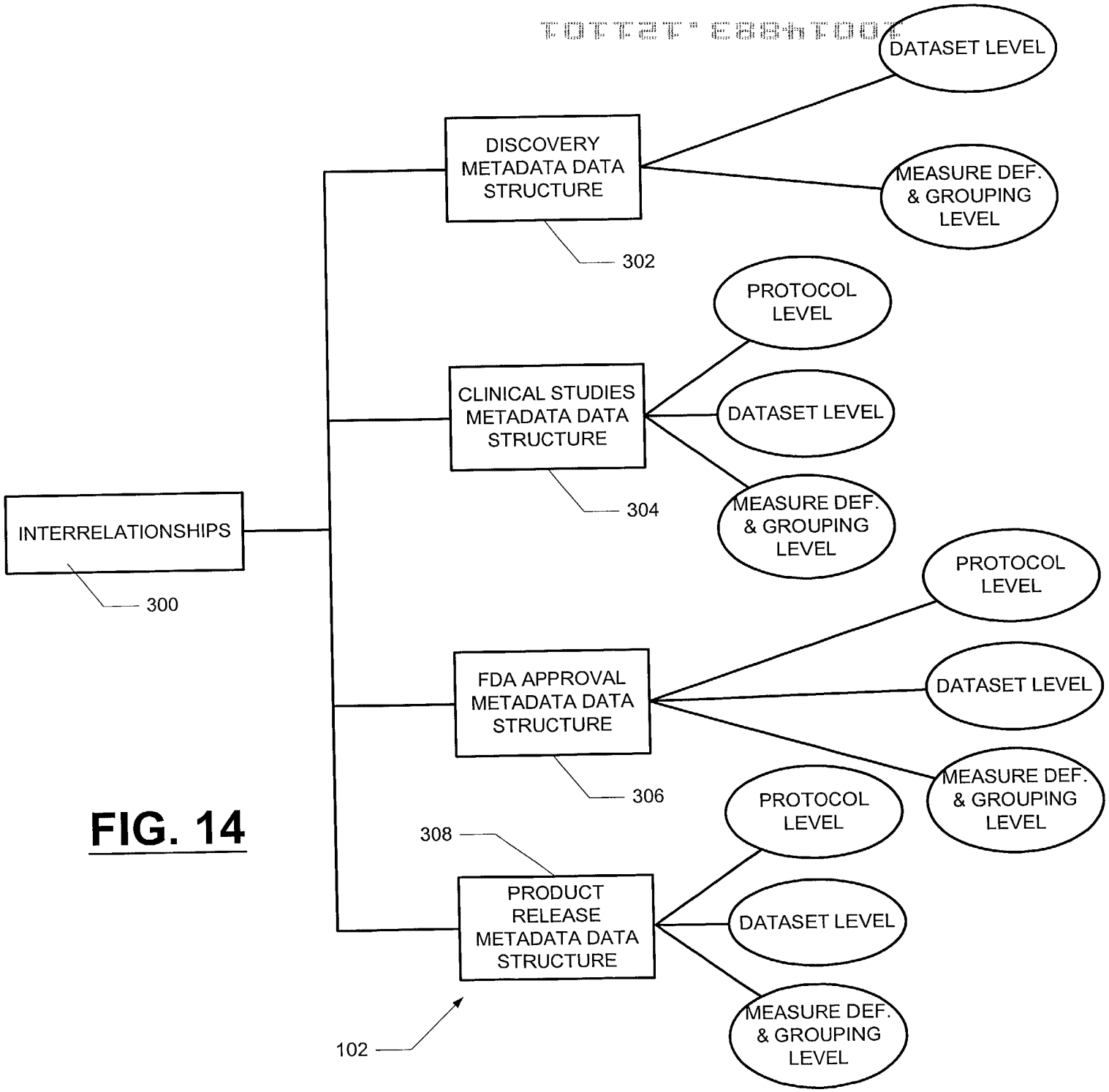

INTERRELATIONSHIPS
300
DISCOVERY METADATA DATA STRUCTURE
302
DATASET LEVEL
MEASURE DEF. & GROUPING LEVEL
CLINICAL STUDIES METADATA DATA STRUCTURE
304
PROTOCOL LEVEL
DATASET LEVEL
MEASURE DEF. & GROUPING LEVEL
FDA APPROVAL METADATA DATA STRUCTURE
306
PROTOCOL LEVEL
DATASET LEVEL
MEASURE DEF. & GROUPING LEVEL
308
PRODUCT RELEASE METADATA DATA STRUCTURE
PROTOCOL LEVEL
DATASET LEVEL
MEASURE DEF. & GROUPING LEVEL
102

FIG. 14

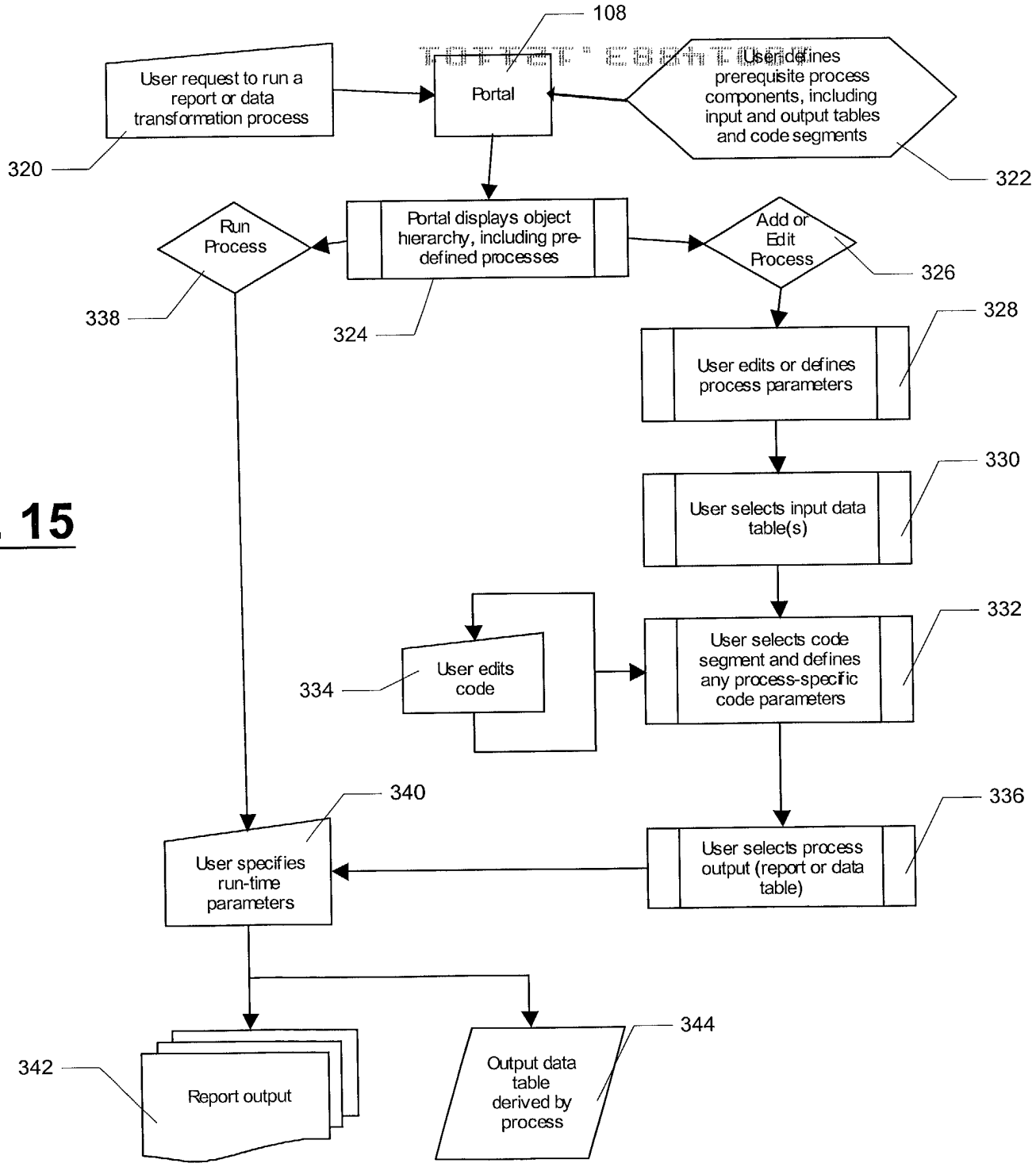

108
User request to run a report or data transformation process
Portal
User defines prerequisite process components, including input and output tables and code segments
320
322
Run Process
Portal displays object hierarchy, including pre-defined processes
Add or Edit Process
326
338
324
328
User edits or defines process parameters
330
User selects input data table(s)
332
User edits code
334
User selects code segment and defines any process-specific code parameters
340
336
User specifies run-time parameters
User selects process output (report or data table)
342
Report output
344
Output data table derived by process

FIG. 15

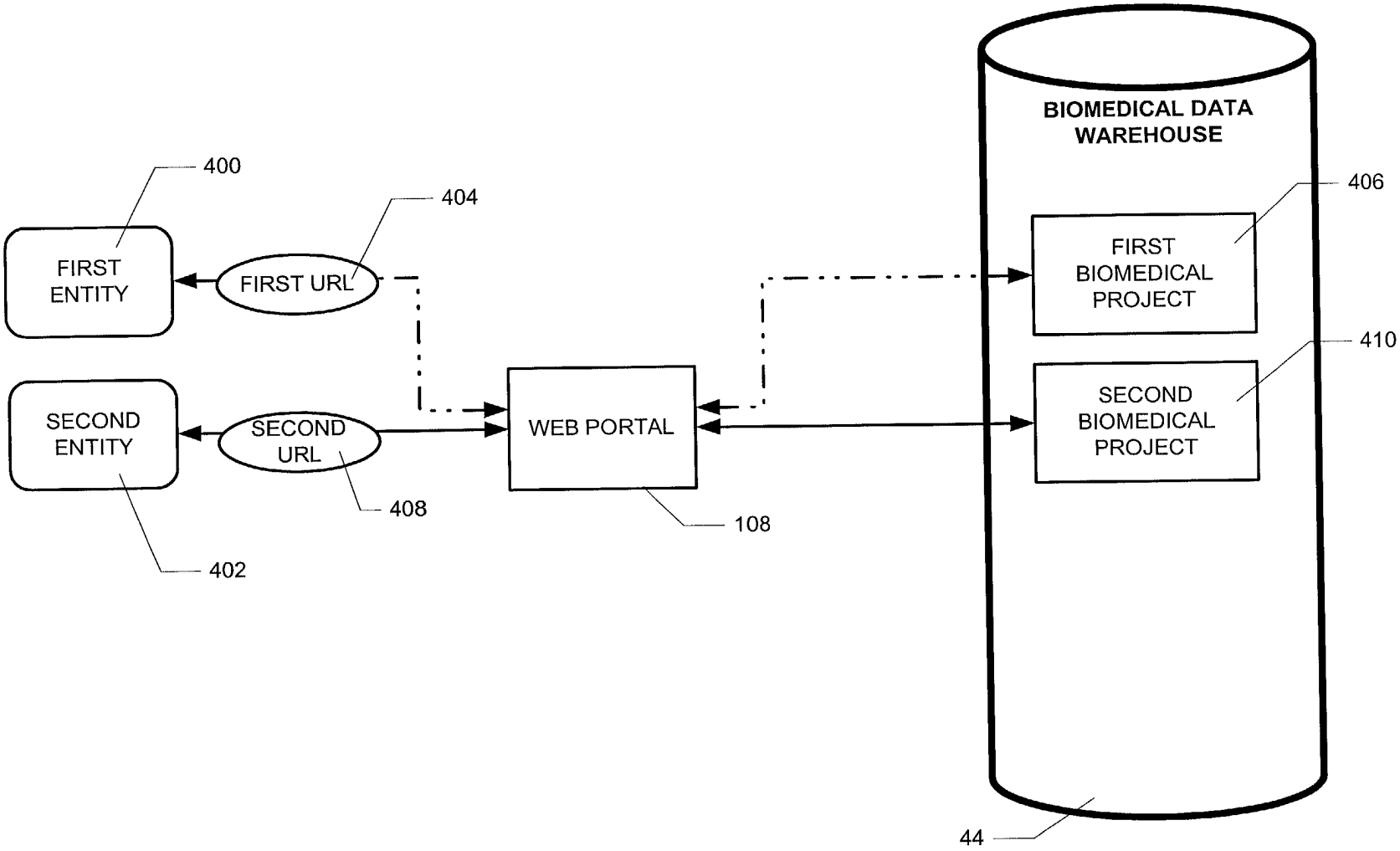

BIOMEDICAL DATA WAREHOUSE
400
404
406
FIRST ENTITY
FIRST URL
FIRST BIOMEDICAL PROJECT
410
SECOND ENTITY
SECOND URL
WEB PORTAL
SECOND BIOMEDICAL PROJECT
408
108
402
44

FIG. 16

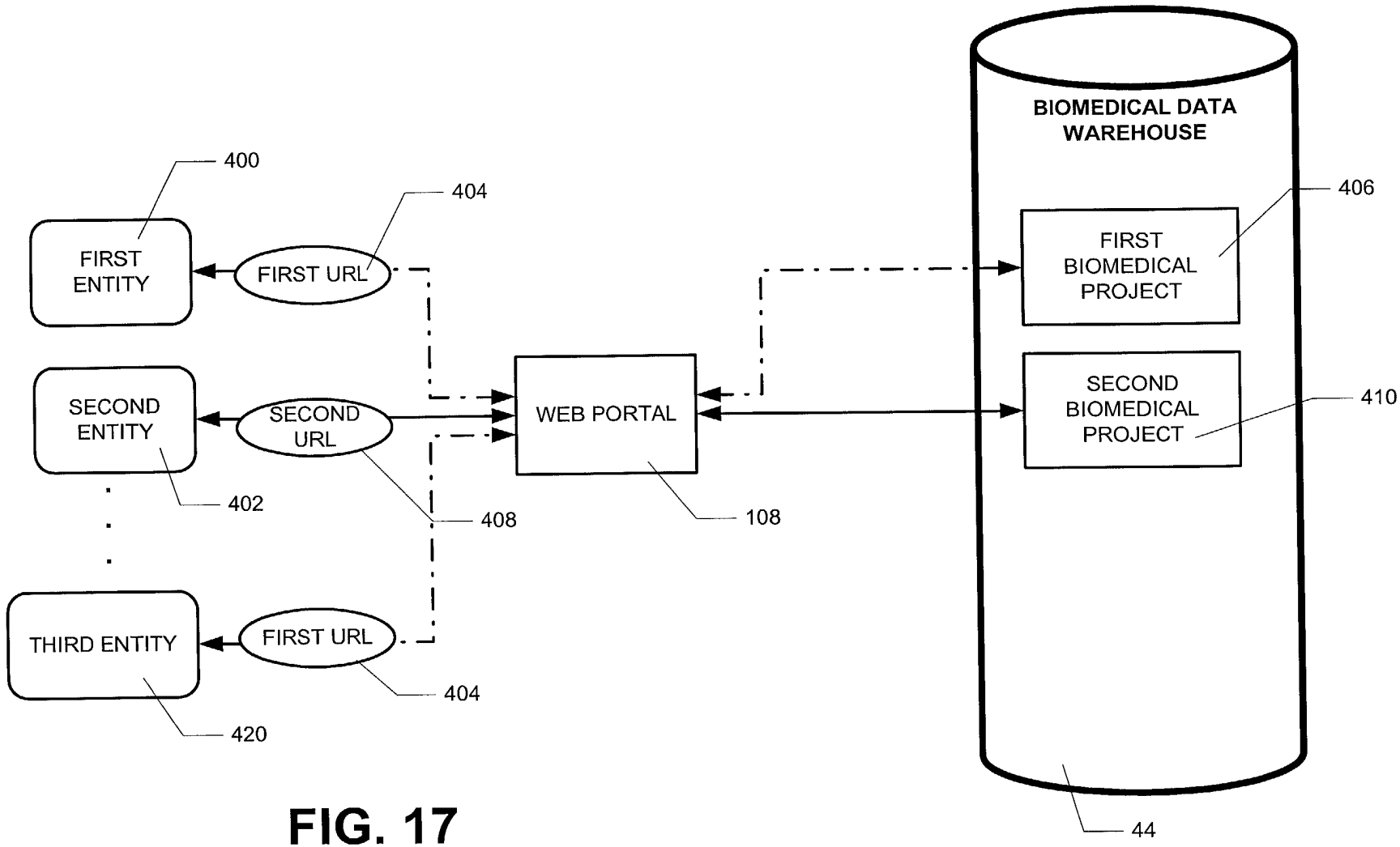

BIOMEDICAL DATA WAREHOUSE
400
404
406
FIRST ENTITY
FIRST URL
FIRST BIOMEDICAL PROJECT
SECOND ENTITY
SECOND URL
WEB PORTAL
SECOND BIOMEDICAL PROJECT
410
402
408
108
THIRD ENTITY
FIRST URL
404
420
44

FIG. 17

FIG. 18

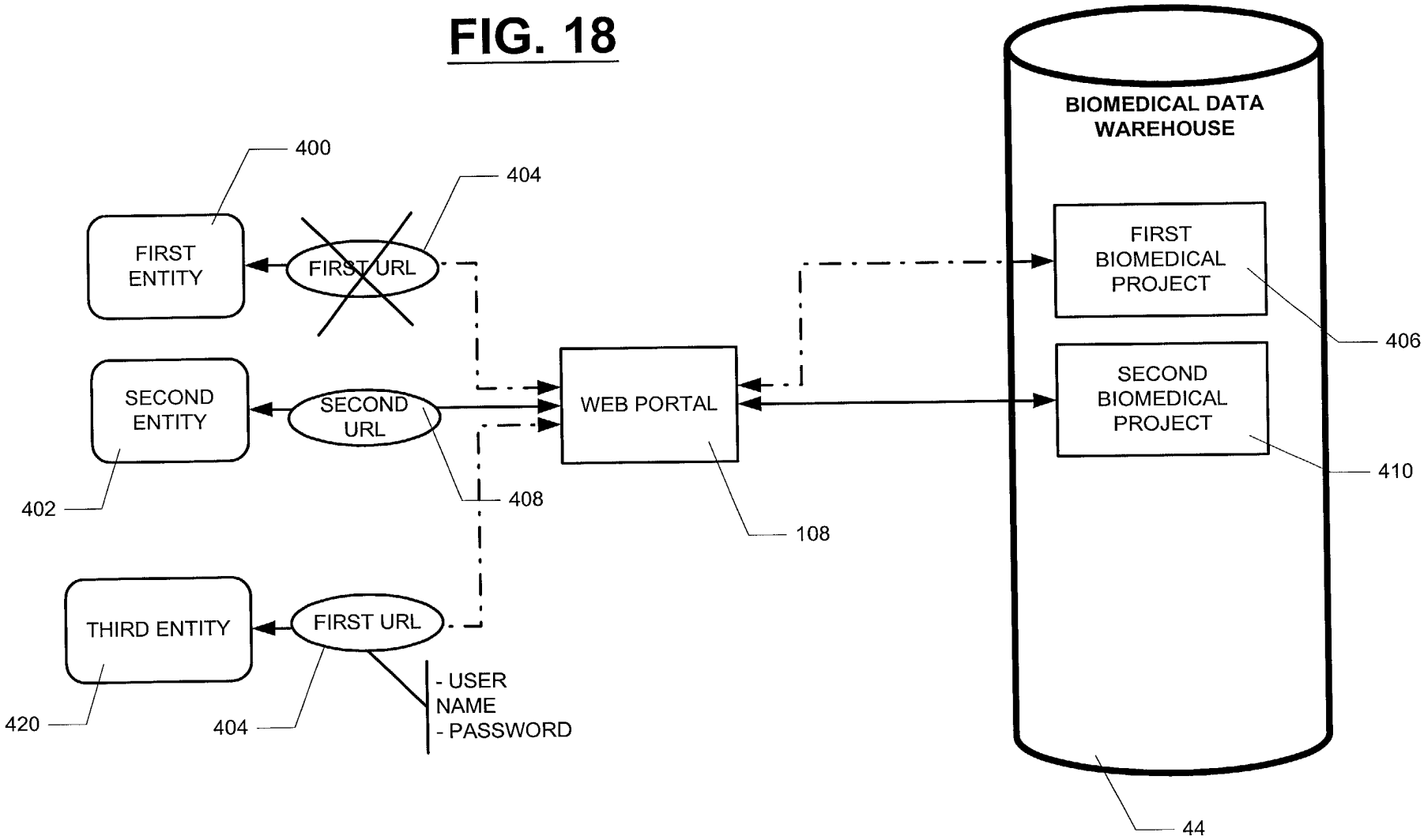
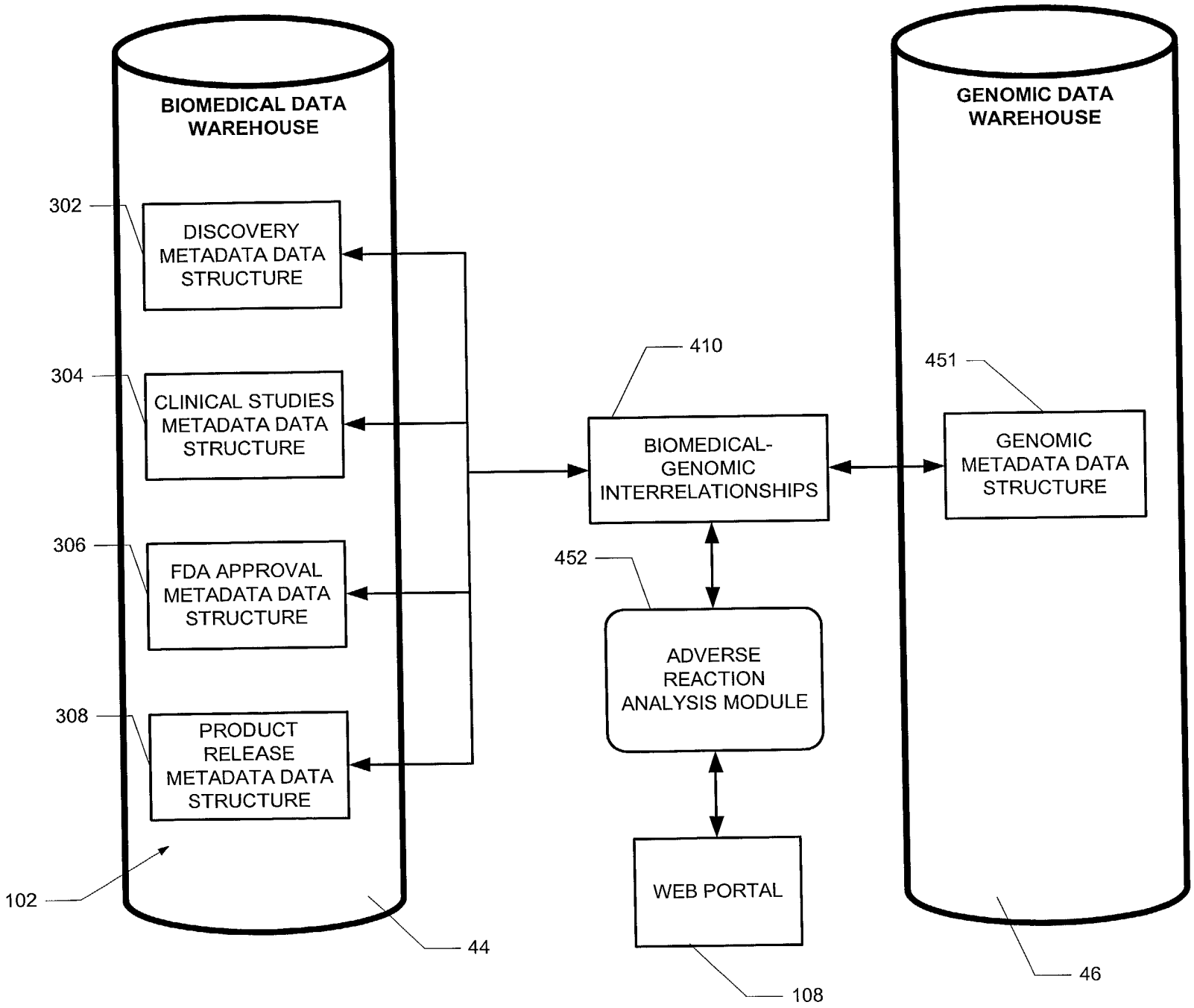

400
404
FIRST ENTITY
FIRST URL
SECOND ENTITY
SECOND URL
402
408
WEB PORTAL
108
BIOMEDICAL DATA WAREHOUSE
FIRST BIOMEDICAL PROJECT
406
SECOND BIOMEDICAL PROJECT
410
THIRD ENTITY
FIRST URL
- USER NAME
- PASSWORD
420
404
44

FIG. 19


BIOMEDICAL DATA WAREHOUSE
302
DISCOVERY METADATA DATA STRUCTURE
304
CLINICAL STUDIES METADATA DATA STRUCTURE
306
FDA APPROVAL METADATA DATA STRUCTURE
308
PRODUCT RELEASE METADATA DATA STRUCTURE
102
44
410
BIOMEDICAL-GENOMIC INTERRELATIONSHIPS
452
ADVERSE REACTION ANALYSIS MODULE
WEB PORTAL
108
GENOMIC DATA WAREHOUSE
451
GENOMIC METADATA DATA STRUCTURE
46

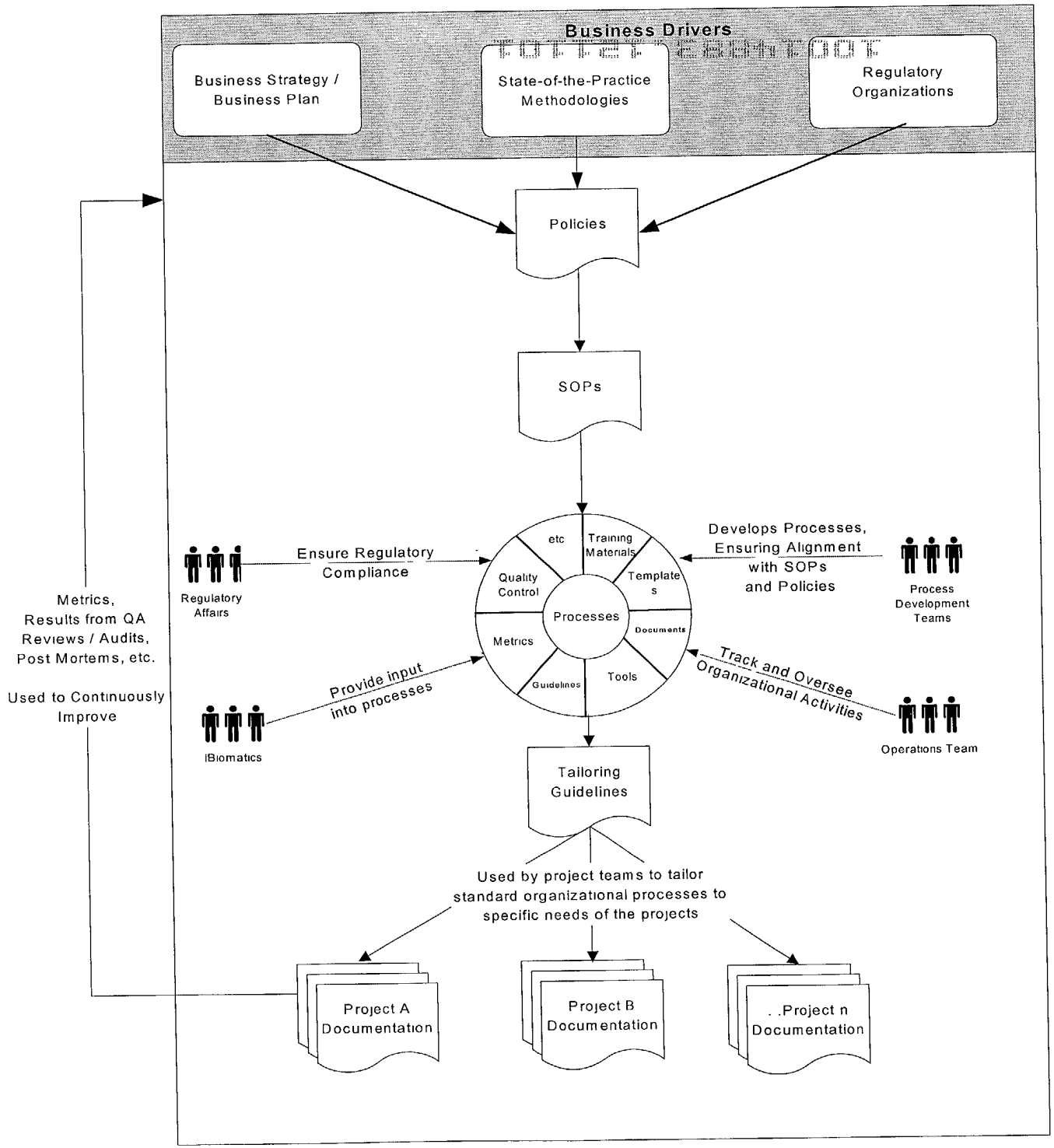

Business Drivers
Business Strategy / Business Plan
State-of-the-Practice Methodologies
Regulatory Organizations
Policies
SOPs
Metrics, Results from QA Reviews / Audits, Post Mortems, etc.
Used to Continuously Improve
Regulatory Affairs
Ensure Regulatory Compliance
etc
Training Materials
Quality Control
Templates
Processes
Documents
Metrics
Guidelines
Tools
Develops Processes, Ensuring Alignment with SOPs and Policies
Process Development Teams
Provide input into processes
IBiomatics
Track and Oversee Organizational Activities
Operations Team
Tailoring Guidelines
Used by project teams to tailor standard organizational processes to specific needs of the projects
Project A Documentation
Project B Documentation
. .Project n Documentation

FIG. 20